K113524

MAY - 8 2012

510(k) Summary – Calcium Generation 2 Assay

Introduction

Roche Diagnostics Corporation hereby submits this 510(k) to provide notification of our intent to market the Calcium Generation 2 assay. The original 510(k) summary was submitted by Kathie Goodwin on November 28, 2011. This revised version is a result of the changes that occurred based on Roche's hold response.

Submitter, name, address, contact

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New Primary Contact person: Lisa Klinedinst
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Date prepared: March 30, 2012

Device name

Proprietary name: Calcium Gen. 2

Common name: CA2

Classification name: Calcium Test System under 21 CFR 862.1145

Product code: CHW

Device description

The Calcium Gen. 2 test system employs a photometric test method where calcium ions react with a calcium specific polyamino carboxylic acid under alkaline conditions to form a complex. This complex reacts in the second step with EDTA. The calcium concentration is directly proportional to the change in absorbance which is measured photometrically.

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510(k) Summary – Calcium Generation 2 Assay, continued

Intended use

The Calcium Gen.2 assay is an in vitro diagnostics reagent system intended for quantitative determination of calcium in human serum, plasma and urine on Roche/Hitachi cobas c systems.

Predicate device

Roche claims substantial equivalence to the currently marketed Calcium test system cleared in K921661.

Substantial equivalence

The following table compares the features of the draft device with the predicate device.

Feature	Predicate Device: Calcium (K921661)	Draft Device: Calcium Gen. 2
Intended Use	In vitro test for the quantitative determination of calcium in human serum, plasma and urine on Roche automated clinical chemistry analyzers.	same
Sample Types	Serum, Heparin Plasma, and Urine	Serum, Li-Heparin Plasma and Urine
Instrument Platform	Roche Hitachi analyzers	cobas c 501 analyzer
Calibrator	Calibrator f.a.s.	same
Calibration Frequency	Every 3 days if the reagent bottles are onboard the analyzer for more than 3 days; after reagent bottle change if the previous bottles were onboard the analyzer for more than 3 days; after reagent lot change; and as required following quality control procedures	After reagent lot change and as required following quality control procedures.
Calibration Mode	Two point linear	same

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510(k) Summary – Calcium Generation 2 Assay, continued

Substantial equivalence (continued)

Feature	Predicate Device: Calcium (K921661)	Draft Device: Calcium Gen. 2
Controls	• Preinorm U Plus • Precipath U Plus • Preinorm U • Precipath U	• Preinorm U Plus • Precipath U Plus • Preinorm U • Precipath U • PreciControl ClinChem Multi1 • PreciControl ClinChem Multi2
Reagent Active Ingredients	o-Cresolphthalein complexone, 8-hydroxyquinoline, HCl acid	5-nitro-5'-methyl-BAPTA
Reagent Stability	**Unopened** 15-25°C until expiration date **On-board in use** R1: 42 days R2: 90 days	**Unopened** 2-8°C until expiration date **On-board in use** 42 days
Measuring Range	**Serum/Plasma:** 0.2 – 20 mg/dL **Urine:** 0.48 – 48 mg/dL	**Serum/Plasma:** 0.8 – 20.1 mg/dL **Urine:** 0.8 – 30.1 mg/dL
Lower Limits of Measure	Not Established	Serum/plasma LoB: 0.4 mg/dL LoD: 0.8 mg/dL LoQ: 0.8 mg/dL Urine LoB: 0.4 mg/dL LoD: 0.8 mg/dL LoQ: 0.8 mg/dL

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510(k) Summary – Calcium Generation 2 Assay, continued

Substantial equivalence (continued)

<table>
<tr><th>Feature</th><th>Predicate Device:
Calcium (K921661)</th><th>Draft Device:
Calcium Gen. 2</th></tr>
<tr><td>Precision</td><td>
Serum/plasma
<table>
<tr><th></th><th>Mean</th><th>CV
Repeatability</th></tr>
<tr><td>Human serum</td><td>8.49 mg/dL</td><td>0.9%</td></tr>
<tr><td>Precitrol N</td><td>9.18 mg/dL</td><td>0.7%</td></tr>
<tr><td>Precitrol A</td><td>13.3 mg/dL</td><td>0.4%</td></tr>
</table>
<table>
<tr><th></th><th>Mean</th><th>CV
Intermediate precision</th></tr>
<tr><td>Human serum</td><td>8.41 mg/dL</td><td>1.6%</td></tr>
<tr><td>Precitrol N</td><td>9.12 mg/dL</td><td>1.7%</td></tr>
<tr><td>Precitrol A</td><td>13.1 mg/dL</td><td>1.1%</td></tr>
</table>
Urine
<table>
<tr><th></th><th>Mean</th><th>CV
Repeatability</th></tr>
<tr><td>Human urine</td><td>14.3 mg/dL</td><td>0.8%</td></tr>
<tr><td>Control Urine 1</td><td>6.12 mg/dL</td><td>1.2%</td></tr>
<tr><td>Control Urine 2</td><td>10.8 mg/dL</td><td>0.9%</td></tr>
</table>
<table>
<tr><th></th><th>Mean</th><th>CV
Intermediate precision</th></tr>
<tr><td>Human urine</td><td>14.0 mg/dL</td><td>1.4%</td></tr>
<tr><td>Control Urine 1</td><td>6.04 mg/dL</td><td>1.6%</td></tr>
<tr><td>Control Urine 2</td><td>10.7 mg/dL</td><td>1.4%</td></tr>
</table>
</td><td>
Serum/plasma
<table>
<tr><th></th><th>Mean</th><th>CV
Repeat-ability</th><th>CV
Intermediate precision</th></tr>
<tr><td>Human serum 1</td><td>2.4 mg/dL</td><td>2.0%</td><td>2.5%</td></tr>
<tr><td>Human serum 2</td><td>10.2 mg/dL</td><td>0.8%</td><td>0.9%</td></tr>
<tr><td>Human serum 3</td><td>17.9 mg/dL</td><td>0.8%</td><td>0.9%</td></tr>
<tr><td>Precinorm U</td><td>9.0 mg/dL</td><td>0.8%</td><td>0.8%</td></tr>
<tr><td>Precipath U</td><td>14.1 mg/dL</td><td>0.8%</td><td>0.9%</td></tr>
</table>
Urine
<table>
<tr><th></th><th>Mean</th><th>CV
Repeat-ability</th><th>CV
Intermediate precision</th></tr>
<tr><td>Human urine 1</td><td>2.3 mg/dL</td><td>3.0%</td><td>3.1%</td></tr>
<tr><td>Human urine 2</td><td>15.7 mg/dL</td><td>1.1%</td><td>1.2%</td></tr>
<tr><td>Human urine 3</td><td>20.8 mg/dL</td><td>0.9%</td><td>1.1%</td></tr>
<tr><td>Human urine 4</td><td>24.4 mg/dL</td><td>1.3%</td><td>1.3%</td></tr>
<tr><td>Control Level 1</td><td>7.4 mg/dL</td><td>1.3%</td><td>1.5%</td></tr>
<tr><td>Control Level 2</td><td>10.9 mg/dL</td><td>1.1%</td><td>1.3%</td></tr>
</table>
</td></tr>
<tr><td>Expected Values</td><td>
Serum/plasma:
8.6-10.2 mg/dL

24 Hour Urine:
100-321 mg/24 h, corresponding to 6.8-21.3 mg/dL

Reference range acc. To Tietz
Serum/plasma:
Children (0-10 days): 7.6-10.4 mg/dL
Children (10 days -2 years): 9.0-11.0 mg/dL
Children (2 years-12 years): 8.8-10.8 mg/dL
Children (12-18 years): 8.4-10.2 mg/dL
Adults (18-60 years): 8.6-10.0 mg/dL
Adults (60-90 years): 8.8-10.2 mg/dL
Adults (>90 years): 8.2-9.6 mg/dL

Urine
100-300 mg/24 h with normal food intake
</td><td>
Reference range acc. To Tietz
Serum/plasma:
Children (0-10 days): 7.6-10.4 mg/dL
Children (10 days -2 years): 9.0-11.0 mg/dL
Children (2 years-12 years): 8.8-10.8 mg/dL
Children (12-18 years): 8.4-10.2 mg/dL
Adults (18-60 years): 8.6-10.0 mg/dL
Adults (60-90 years): 8.8-10.2 mg/dL
Adults (>90 years): 8.2-9.6 mg/dL

Urine
100-300 mg/24 h with normal food intake
</td></tr>
</table>

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510(k) Summary – Calcium Generation 2 Assay, continued

Substantial equivalence (continued)

Feature	Predicate Device: Calcium (K921661)	Draft Device: Calcium Gen. 2
Interferences	**Serum/Plasma** **Icterus:** no significant interference up to an I index of 60 **Hemolysis:** no significant interference up to and H index of 1000 **Lipemia:** no significant interference up to an L index of 1000 **Drugs:** Drugs containing strontium salts may lead to significantly increased calcium results. **Other:** -Intravenously administered contrast media for MRI contain chelating complexes which may interfere with the determination of calcium. -A sharp decrease in calcium values was observed when gadodiamide was administered. Follow the instructions of the manufacturer with regard to the retention time of the contrast medium. -In very rare cases gammopathy, in particular type IgM (Waldenstrom's macroglulinemia), may cause unreliable results. --- **Urine:** **Drugs:** Drugs containing strontium salts may lead to significantly increased calcium results.	**Serum/Plasma** Same Endogenous Interferent Claims **And in Addition:** -The interference of intravenously administered gadolinium containing MRI (magnetic resonance imaging) contrast media was tested (Omniscan®, Optimark®) but no interference was found at the therapeutic concentration. Interference at higher concentrations was observed. -In very rare cases gammopathy, in particular type IgM (Waldenstrom's macroglulinemia), may cause unreliable results. --- **Urine:** **Icterus:** no significant interference up to a conjugated bilirubin concentration of 60 mg/dL **Hemolysis:** no significant interference up to a hemoglobin concentration of 1000 mg/dL **Magnesium:** no significant interference up to a concentration of 60 mmol/L **Drugs:** No interference was found at therapeutic concentrations using common drug panels. **Other:** -The interference of intravenously administered gadolinium containing MRI (magnetic resonance imaging) contrast media was tested (Omniscan®, Optimark®). For Omniscan® no interference was observed at the therapeutic concentration, but there was interference at higher concentrations. For Optimark® interference was observed at therapeutic and higher concentrations.

End of Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Roche Diagnostics Operations, Inc.
c/o Lisa Klinedinst
9115 Hague Road
P. O. Box 50416
Indianapolis, IN 46250

MAY - 8 2012

Re: k113521
Trade Name: Calcium Gen.2
Regulation Number: 21 CFR §862.1145
Regulation Name: Calcium Test System
Regulatory Class: Class II
Product Codes: CHW
Dated: March 30, 2012
Received: April 2, 2012

Dear Ms. Klinedinst:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113521

Device Name: Roche/Hitachi cobas c Calcium Gen.2

Indications For Use:

The Calcium Gen.2 assay is an in vitro diagnostics reagent system intended for the quantitative determination of calcium in human serum, plasma, and urine on Roche/Hitachi cobas c systems. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease, and tetany.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113521